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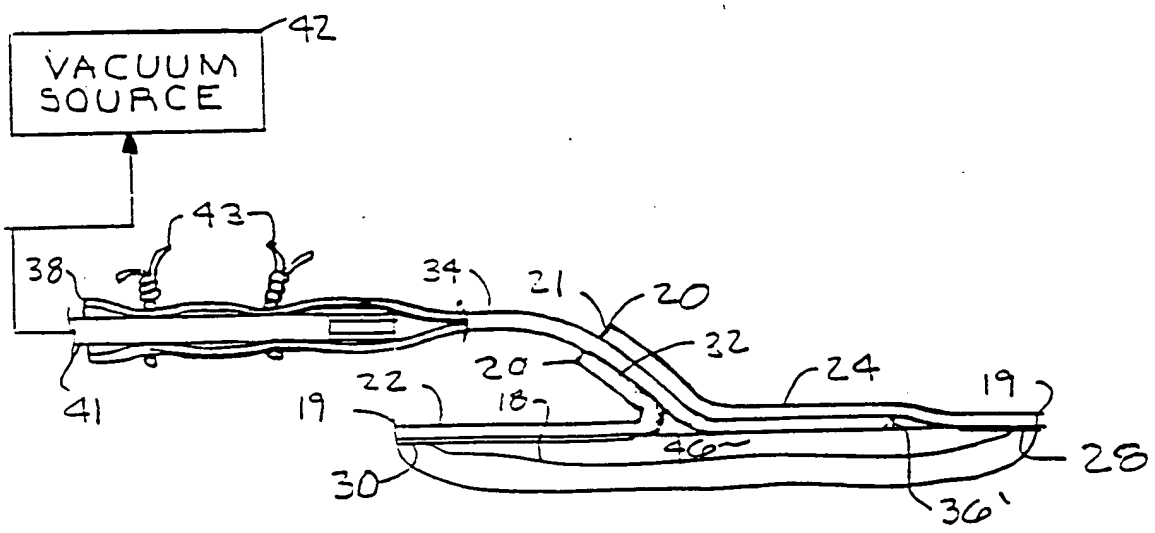
(54) Title: FLUIDIC CONNECTION SYSTEM AND METHOD



(57) Abstract

A wound dressing (10) includes a cover membrane (22) comprising a semi-permeable material with an adhesive-coated (30) skin contact surface (28). An opening (32) is formed in an interior portion of the membrane. An intermediate layer of material may be placed between the wound and the membrane contact surface for either absorbing fluids from the wound, e.g. with a hydrocolloid or hydrophilic material, or for passing such fluids to the opening with a synthetic material, e.g. rayon. A tube (34) includes a proximate end (36) fluidically communicating with the wound through the membrane opening. A distal end (38) of the tube is adapted for connection to a suction source (47) for draining the wound or a fluid source for introducing liquid medication to the wound. Both evacuation and introduction can be either active or passive. A wound treatment method is also disclosed.

FLUIDIC CONNECTION SYSTEM AND METHOD

Cross-Reference to Related Application

Continuation-in-Part of U. S. Patent Application Serial Number 07/332,699, filed April 3, 1989.

Background of the Invention

1. Field of the Invention.

The present invention relates generally to fluidic connection systems, and in particular to systems for draining liquids from and introducing liquids to patients.

2. Description of the Relevant Art.

Various types of fluidic connection systems have heretofore been devised to meet the requirements of particular applications. In the medical field, fluidic connection systems find many applications, including wound dressings and systems for introducing fluids to and removing fluids from patients.

Wound dressings are typically applied over various types of wounds to promote healing and to reduce the risk of infection. Although various types of dressing materials have been successfully employed, membranes comprising semi-permeable materials are often preferred because they can increase patient comfort and lower the risk of infection. Semi-permeable membranes generally pass moisture vapors, but are generally impervious to liquids. Thus, they can promote healing by permitting a wound site to "breathe".

who are incontinent or have otherwise lost voluntary control of their bladder functions, e.g. a paraplegic with a spasdic bladder condition. However, patients fitted with urethral catheters are often subjected to risks of bladder and urinary tract infections.

To avoid some of these infection risks, condom catheters have been devised which typically include a body for placement over the penis and a bellows-type distal end for resisting kinks and for connection to a drain tube. However, condom catheters are susceptible to slippage and can be difficult to maintain in place unless they are taped to the patient's penis. Furthermore, there can be difficulties in effectively draining sudden surges of urine, which often back up and cause leakage problems.

Heretofore there has not been available a fluidic connection system and method with the advantages and features of the present invention.

Summary of the Invention

In the practice of the present invention, a fluidic connection system is provided which includes a semi-permeable membrane including a pair of panels each having a perimeter and an edge strip. The membrane is formed by connecting the panel edge strips together to form a seam extending transversely across the membrane. The panels and the membrane include inner and outer surfaces. A tube opening extends through the seam between the panel edge

membrane. Fluids from a draining wound can be evacuated through the tube and liquid medication and irrigation can be introduced through the tube to the wound site. The fluid evacuation and introduction steps of the method can each be accomplished both actively and passively, and can be alternated in a wound treatment procedure. Additional steps that can be included in the method of the present invention include extending an inner conduit through the sheath and sealing the inner conduit and the sheath together in a fluid-tight engagement.

Objects and Advantages of the Preferred Embodiments

The principle objects and advantages of the present invention include: to provide a wound dressing; to provide such a dressing which promotes the evacuation of drainage fluids; to provide such a dressing which permits the introduction of liquid medications; to provide such a dressing which includes a semi-permeable membrane for releaseable, adhesive attachment to the skin surface surrounding a wound; to provide such a dressing which protects against infection; to provide such a dressing which promotes healing; to provide such a dressing which is economical to manufacture, efficient in operation, capable of a long operating life and particularly well adapted for the proposed usage thereof; to provide a wound treatment method; to provide a fluidic connection system and method; to provide such a connection system and method which are adaptable to various applications; to provide such a connection system and method which can be utilized as a

Fig. 6 is an enlarged, fragmentary, vertical, cross-sectional view of the dressing, particularly showing the tube connected to a vacuum source.

Fig. 7 is an enlarged, fragmentary, vertical, cross-sectional view of the dressing, particularly showing a resealable injection port mounted on a distal end of the tube.

Fig. 8 is a top perspective view of a wound dressing comprising a first modified embodiment of the present invention.

Fig. 9 is a top plan view of a wound dressing comprising a second modified embodiment of the present invention with an intermediate material layer between the wound site and a cover membrane.

Fig. 10 is an enlarged, fragmentary, vertical, cross-sectional view of the second modified wound dressing embodiment, taken generally along line 10-10 in Fig. 9.

Fig. 11 is a perspective view of a fluidic connection system comprising a third modified embodiment of the present invention, shown in combination with a drain conduit and fluid connection vessel for use as a condom catheter and urine collection system.

Fig. 12 is a top plan view of the connection system being applied as a condom catheter.

Fig. 13 is an enlarged, vertical, cross-sectional view of the connection system taken generally along line 13-13 in Fig. 12.

Fig. 14 is an enlarged, fragmentary, vertical, cross-sectional view of the connection system, particularly showing a funnel end of an inner conduit.

Referring to the drawings in more detail, the reference numeral 10 generally designates a wound dressing embodying the present invention. The dressing 10 is adapted for protecting and treating a variety of wounds, such as that shown at 12. Without limitation on the generality of the useful applications of the present invention, the dressing 10 may be applied over burns, cuts, scrapes and ulcers of various types, e.g. diabetic, decubitus, peripheral vascular disease, venous stasis and trauma ulcers.

Skin ulcers are a common problem among many diabetics, and are often brought on by poor blood circulation and nerve damage associated with diabetes. The treatment of such ulcers often involves grafting skin from a relatively healthy donor site to an ulcerous wound site. Split thickness surgical skin graft techniques may be employed to obtain skin grafts from donor sites that can then heal spontaneously. Full thickness skin grafts, on the other hand, generally require closure of the donor site. It will be appreciated from the following description that the wound dressing and treatment method of the present invention is particularly well adapted for the protection and regeneration of skin graft donor sites by providing a single dressing which facilitates both fluid drainage and growth factor introduction.

The wound site 12 is surrounded by healthy skin 16. A fibrin layer 18 forms at the wound site 12 from fibrinogen by the action of thrombin and the clotting of blood (Figs. 2 and 6). Surgical wounds, including those associated with

A tube or sheath 34 includes a proximate end 36 located under the membrane 22 and a distal or free end 38. The tube 34 can be inserted through the seam 21 which forms an opening 32 between the panel edge strips 20 at approximately the center of the membrane 22. A relatively short length of the tube 34 adjacent to its proximate end 36 is shown under the membrane 22, but greater lengths of the tube 34 could be placed under the membrane 22. As shown in Fig. 5, the tube proximate end 36 is open, and adjacent to the proximate end 36 an opening is formed. Preferably the tube opening 39 projects downwardly, i.e. away from the membrane skin contact surface 28. The short length of the tube 34 which is located under the membrane 22 can be releaseably secured to the skin contact surface 28 by the adhesive coating 30, preferably with the tube opening 39 facing downwardly.

The tube 34 can comprise, for example, a flexible, plastic tube of the type that is commonly used as a protective sheath for protection of sterility for percutaneous intravenous catheter placement. Such sheaths are commercially available from Aero International, Inc. of Reading, Pennsylvania.

At its distal end 38, the tube 34 is adapted for: 1) closure with a variety of suitable closure devices; 2) connection to various active and passive fluid collection devices for draining and evacuating fluid from the wound site; and 3) connection to various fluid source devices for actively and passively introducing fluid to the wound site.

Fig. 5 shows a bifurcated clip 40 for releaseably closing and sealing the tube distal end 38, which is folded upon itself as shown.

are commercially available for supplementing the bonding action of the adhesive coating 30 in bonding the membrane contact surface 28 to the healthy skin 16. The membranes 22 may be provided in various sizes to accomodate wounds of different sizes. A sufficiently large membrane 22 should normally be selected to provide ample overlap of the perimeter 26 over the healthy skin 16 to insure a good bond therebetween.

The tube distal end opening 39 may be placed directly over the approximate center of the wound site 12, or it may be placed eccentrically or at a depending location with respect to the wound site 12. A dependent or lower position for the opening 39 with respect to the wound site 12 may be preferred to facilitate fluid drainage. The dressing 10 may be applied promptly after a wound is inflicted, e.g. immediately after the graft removal procedure and a skin graft operation. To reduce the risk of infection, it may be advisable to promptly cover the open wound site 12. The wound dressing 10 may be kept in a sterile package until it is needed. Such sterile packages and packaging techniques are well known. For example, ethylene oxide may be used to sterilize the dressing 10 prior to placement in a suitable sterile package. The protective backing 23 is removed from the membrane 22, thereby exposing its adhesive-coated contact surface 28.

With the membrane 22 thus secured, a chamber 46 is formed between the wound site 12 and the membrane contact surface 28, and is surround by the membrane perimeter 26. The chamber 46 fluidically communicates with the membrane opening 32. In an evacuation mode of operation, such as

International, Inc. of Reading, Pennsylvania. Such connecting devices are commonly used in connection with the intravenous introduction of various liquid solutions.

In an active introduction mode of operation, solutions may be pumped through the tube 34 into the chamber 46 for application to the wound site 12.

The evacuation and introduction treatment steps can be timed and sequenced as necessary to achieve the treatment objectives. For example, treatment of a skin graft donor site may involve fluid withdrawal and drainage for about two days immediately following the skin graft operation, followed by treatment steps comprising the introduction of antibiotics and/or growth factor solutions to the wound site. The evacuation and introduction steps can be alternated, and the intervals between such steps can be progressively increased or decreased as necessary to facilitate healing. As the wound heals, progressively smaller amounts of fluid will ooze therefrom and the frequency and duration of the drainage operations can be correspondingly reduced and finally discontinued altogether.

It will be appreciated that the wound dressing and treatment method of the present invention are broadly concerned with introducing fluid to wound sites and evacuating fluid therefrom. The fluid introduction and evacuation procedures described herein can be performed indefinitely without having to change the dressing 10. The tube 34 cooperates with the membrane 22 to permit the same dressing 10 to be used for both procedures, which may be

alte[redacted]d as often as necessary. [redacted]fection risks and patient discomfort can be reduced by minimizing wound dressing changes.

The removal of toxins and bacteria from wounds is an important aspect of the fluid drainage phase of the healing process. The wound dressing of the present invention facilitates removal of serum and other secretions to minimize the risk of infecting the wound site and macerating the tissue thereat. Growth factor solutions can be important in promoting healing, and antibiotics can be important in preventing and treating infection. Hence, a comprehensive wound treatment can be implemented with the wound dressing and treatment method of the present invention.

The wound dressing 10 can be employed to irrigate a wound whereby fluid is introduced and then removed.

The operation of the wound dressing 10 is largely a matter of fluid mechanics, and the function of the wound dressing 10 would probably be determined by such factors and variables as: 1) fluid viscosity; 2) permeability of the membrane 22; 3) cross-sectional area of the tube 34 and the area of its opening 39; 4) the integrity of the seal around the membrane perimeter 26; 5) the drawing power of the suction or vacuum source 42; 6) coagulation of the serum or other fluid; 7) the area of the fluid collection chamber 46; 8) the length of the tube 34; and 9) gravity and the relative positions of various components. Naturally, varying one or more of these factors or variables could change the operation of the system. It is anticipated that, applying such well-known principles of fluid mechanics, all

of the wound dressing components could be properly sized and designed. For example, the tube opening 39 could be enlarged, or multiple openings could be provided to increase the rate of fluid flow into the tube 34. The rate of fluid flow can further be increased by locating the tube distal end 38 at a dependent area within the chamber 46, i.e. below the level of most of the wound site 12. The tube 34 can extend downwardly to a collection site below the level of the wound site 12 to facilitate gravity drainage.

It is further anticipated that some fluids will resist drainage because of their viscosities or because they tend to coagulate. Drainage of such fluids can be effected by irrigating the wound site 12.

IV. First Modified Embodiment 110

Figure 8 shows a wound dressing 110 comprising a first modified embodiment of the present invention wherein a relatively small membrane 122 is provided and functions as a patch for a larger wound cover 115 with an opening 117 for receiving a distal end 138 of a tube 134. The primary wound cover 115 is selected to cover a wound site 112, and is placed thereover in the normal fashion. The wound dressing 110 can be placed on the primary wound cover 115 in a location chosen to enhance fluid introduction and/or evacuation. For example, to enhance the evacuation of fluid by gravity, it may be desirable to form the opening 117 at a relatively low position of the wound site 112. Thus, fluid will tend to flow to the tube 134 by gravity. To facility the introduction and distribution of fluid, it may be

desirable to locate the wound dressing 110 at a relatively high position on the wound cover 115. In fact, two or more wound dressings 110 could be placed on a single, primary wound cover 115, with a lower wound dressing 110 being provided for fluid evacuation and an upper wound dressing 110 being provided for fluid introduction.

In the practice of the treatment method of the present invention, the wound dressing 110 provides for considerable flexibility in locating the wound dressing 110 in an appropriate location on the wound site 112. After the primary wound cover 115 is positioned, the opening 117 is formed at the chosen location and the wound dressing 110 may be applied, much like a patch, with the tube distal end 138 extending through the primary wound cover opening 117. It will be appreciated that wound dressings 110 may be changed as needed without changing the primary wound cover 115.

V. Second Modified Embodiment 210

A wound dressing 210 comprising a second modified embodiment of the present invention is shown in Figs. 9 and 10 and includes an intermediate layer of material 250 between a wound site 212 and a cover membrane 222. The intermediate material layer 250 can comprise a variety of materials with varying properties such as: 1) absorbency; 2) wicking or capillary action; and 3) surface contact action. The intermediate material layer is primarily located in a chamber 146 formed between the wound 212 and the membrane 222.

As a first example of an intermediate material layer 250, several hydrophilic colloid materials (i.e. hydrocolloids) are available which would tend to absorb fluids. For example, Envisan wound cleaning pads and paste are available from Marion Laboratories, Inc. of Kansas City, Missouri and comprise: spherical, hydrophilic Beads of Dextranomer, 0.1 to 0.3mm in diameter; polyethylene glycol 3000 in the pad; polyethylene glycol 600; and water QS enclosed in a polyamide net bag in the pad or available in a metal foil packet for the paste. The Envisan dextraminer beads function to absorb fluid and facilitate healing by drawing fluid from the wound. Excess fluid can be drained from the intermediate material layer 250 to prolong its effectiveness. Other hydrocolloids are commercially available and may be employed with the wound dressing 210 of the present invention, e.g. dextranimers available under the trademark "Debrisan".

Alternatively, the intermediate material layer 250 can comprise a mesh or sheet of synthetic material which is generally nonabsorbent and would tend to wick fluid from the wound site 212 to a tube distal end 238. For example, rayon available under the trademark Owens non-adherent surgical dressing from the Davis & Geck division of American Cyanamid Company of Danbury, Connecticut could be used to form such an intermediate material layer 250, and material available from Marion Merrell Dow, Inc. of Kansas City, Missouri under the trademark "Envinet" could also be employed. Such materials may be referred to as "surface active", i.e. promoting fibrin sealing on the wound surface. Such materials can also satisfy a capillary purpose whereby fluid

be severed at the surface of the membrane, allowing the closure patch 251 or a similar patch of the same material as the wound dressing 10 to permanently seal the tube site.

VI. Third Modified Embodiment 310

A fluidic connection system 310 comprising a third modified embodiment of the present invention is shown in Figs. 11-16. Without limitation on the generality of useful applications of the fluidic connection system 310, it is shown in connection with a urine collection system 312 and functions as a condom catheter. The connection system 310 generally includes a membrane assembly 314 and a tube assembly 316.

The membrane assembly 314 includes a membrane 318 with an inner or skin contact surface 320, an outer surface 322, a perimeter 324 and an interior portion 326. As shown in Fig. 11, the membrane 318 comprises first and second panels 328, 330.

The panels 328, 330 include inner contact surfaces 329, outer surfaces 331, perimeters 333, and edges 335 with edge strips 332 which are joined together in opposing relation to form a seam 334 extending transversely across the membrane 318 between opposite sides of its perimeter 324. A tube opening 336 extends through the seam 334 approximately in the middle thereof and is open at the membrane inner and outer surfaces 320, 322.

An adhesive layer 338 substantially covers the membrane inner surface 320 and releasably secures a two-piece protective backing 340 (e.g. paper, plastic or some other

conduit for adjustable repositioning. Preferrably the band 372, in either configuration, forms a relatively fluid-tight seal on the conduit 358. The band 372, like the funnel 362, can be slid through the sheath passage 347 for placement proximal to the sheath distal end 350 (Fig. 15). Belt or tie means 378 can be provided for sealingly fastening the sheath 346 to the band 372. As shown in Fig. 15, the belt/tie means 378 can comprise ligatures 380, which can be wrapped around the sheath 346 for tightening it against the band channel 376. Belt/tie means 378 can comprise other suitable fasteners, such as strips with hook-and-loop fasteners (i.e. fasteners available under the trademark "Velcro"), rubber or elastic bands, plastic coated wire twist ties, etc. Multiple bands 372 can be used for connecting and sealing the sheath 346 and the conduit 358.

The conduit distal end can project distally from the sheath distal end 350 (Fig. 15) for connection to tubing 382 by a suitable tubing connector, such as the multi-diameter, double male-ended ("Christmas Tree") connector 384 shown in Figs. 11 and 15. The tubing 382 can lead to a suitable fluid collection vessel 386, which can be positioned remote from the patient.

VII. Applications and Operation

The fluidic connector 310 can be utilized for a variety of fluidic connection applications without the inner tube or conduit assembly 358. For example, the fluidic connection system 310 can function as a wound dressing which operates in a manner similar to the wound dressings 10, 110 and 210

To promote efficient drainage, the connection system 310 can be located at a dependent part of a larger dressing. Alternatively, mechanical suction equipment can be connected for promoting drainage.

Another application of the fluidic connection system 310 is placement over percutaneous catheters, drain tubes, etc. Such tubes present infection risks where they penetrate the skin surface, and can require frequent application of antibiotics to reduce the risk of infection. Percutaneous tubes are often sutured in place at the stab wound locations where they penetrate the skin, and the sutures are further susceptible to infection and can cause swelling and patient irritation. The connection system 310 can be placed over such a percutaneous drain tube or catheter site, with the tubing extending through the sheath 346 in the manner of the conduit 358. The tubing can be secured, for example with one or more bands 372, to protect against traction forces which might otherwise tend to pull the tubing loose. By utilizing a semi-permeable, breathable material for the membrane 318, the skin surrounding a percutanious tubing entry site can be protected against maceation.

For use as a condom catheter in a urine collection system 312, the backing 340 can be removed from the first panel 328, which is then adhesively secured to the ventral side 389 and the lateral sides 391 of a flaccid penis 388 with the urethra orifice or meatus 390 directed at the sheath mouth 356 and the sheath tabs 354 placed on the top and bottom of the glans or penile head 392 (Fig. 13). The

drain to the funnel 362 for evacuation through the conduit 358. Placement and sizing of the sheath 346, the conduit 358 and the band 372 can be adjusted to vary the volume of the interstitial space 397.

The procedure for applying the connection system 310 can be varied according to the conditions of particular patients and the preferences of persons applying it. Properly adherred to a patient, the collection system 310 should be functional for a relatively long period of time, and a semi-permeable membrane material can be utilized to enhance patient comfort.

Other useful applications of the connection system 310 include placement over circumferentially injured limbs and phalanges for draining exudates and/or introducing liquids. For example, an injured hand could be treated by securing the connection system 310 at the wrist, a forearm could be treated by adhering the fluidic connection system 310 at the elbow, etc.

Yet another application is for accessory connections whereby various fluid devices and connectors could be combined in systems attached to patients for appropriate treatment and diagnostic procedures. Such additional accessories include Jackson-Pratt and Blake suction tubing devices, Y-connectors, sampling ports, "Injectaport" devices, fluid pumps and various fluid reservoirs. Hand-actuated bulbs could be placed in the tubing, and valving could be placed where it is needed.

A further application of the fluidic connection system 310 would involve placing the membrane 318 over an intermediate material layer 250 as described in connection

C L A I M S

What is claimed and desired to be secured by Letters Patent is as follows:

1. A fluidic connection system, which comprises:
   (a) covering means with a contact surface and an outer surface;
   (b) adhesion means for releasably attaching said covering means on said contact surface thereof;
   (c) said covering means having an interior portion with an opening extending between and open at the contact and outer surfaces thereof; and
   (d) tube means having a proximate end extending through said opening and terminating adjacent said contact surface and a distal end located outwardly from said outer surface, said tube means fluidically communicating with said contact surface.

2. The invention of Claim 1 wherein said covering means comprises a semi-permeable material.

6. The invention of Claim 2 wherein:

(a) each said panel includes a perimeter and an edge strip, each said edge strip being demarcated by a fold line and folded outwardly from a remainder of a respective panel; and

(b) said tube opening extends between said edge strips.

7. The invention of Claim 1 wherein said tube means proximate end includes:

(a) an opposed pair of longitudinally-extending slits; and

(b) a pair of opposed end tabs each formed between said slits, said tube means proximate end being open between said tabs.

8. The invention of Claim 7 wherein:

(a) each said tab is adhesively connected to a respective panel skin contact surface adjacent to said seam.

12. The invention of Claim 11 wherein said tube clamp means comprises:

(a) an annular band with enlarged proximate and distal ends, a bore extending between said ends and a reduced-diameter waist between said ends, said bore receiving said conduit; and

(b) belt means circling said sheath and securing said sheath to said band waist.

13. The invention of Claim 12 wherein:

(a) said belt means comprises a tensile member wrapped around said sheath and said band waist.

14. The invention of Claim 12 wherein:

(a) said belt means comprises a strap with hook-and-loop fasteners.

15. A fluidic connection system which comprises:

(a) covering means including:

(1) an inner contact surface;

(2) an outer surface;

(3) a first panel including a perimeter and an edge;

(4) a second panel including a perimeter and an edge;

(5) each said panel having an inner contact surface and an outer surface;

16. The invention of Claim 15 wherein said tube means includes:

(a) an outer, tubular sheath connected to said panels at said seam and having a proximate end, a distal end, and a passage extending between said sheath proximate and distal ends; and

(b) an inner, tubular conduit extending through said sheath passage and including conduit proximate and distal ends and a conduit bore extending between said conduit ends.

17. The invention of Claim 16 wherein:

(a) said conduit includes funnel means at its proximate end, said funnel means being adapted to slide longitudinally through said sheath passage.

18. The invention of Claim 16 wherein said tube means includes:

(a) tube clamp means clamping said sheath to said inner conduit.

20. The invention of Claim 19 wherein said tube means includes:

(a) opposed pair of longitudinally-extending slits at said proximate end;

(b) an opposed pair of tabs formed between said slits, each said tab being adhered to a respective panel inner contact surface; and

(c) a mouth open between said tabs at said tube means proximate end.

21. The invention of Claim 20 wherein said tube means includes:

(a) an outer sheath comprising a flexible, collapsible material and having proximate and distal ends with a passage extending therebetween;

(b) an inner, tubular conduit extending through said sheath passage and including conduit proximate and distal ends and a conduit bore extending between said conduit ends;

(c) an annular band with enlarged proximate and distal ends and a bore extending between said end, said bore receiving said conduit and a reduced-diameter waist between said ends; and

(d) belt means circling said sheath adjacent to its distal end and securing said sheath to said band waist.

24. The method of Claim 22 wherein said step of introducing a liquid to said wound includes irrigating said wound.

25. A method of catheterizing a penis, which comprises the steps of:

(a) adhering a membrane comprising first and second panels each including a skin contact surface, an outer surface and a perimeter with an edge to the penis;

(b) forming a seam with opposite ends and extending transversely across said membrane by adhesively engaging said panel contact surfaces along respective strips adjacent to said edges thereof;

(c) providing an opening open at said panel edges and at said contact surface between said interconnected strips and intermediate said seam opposite ends;

(d) extending a sheath with a proximate end having an opposed pair of longitudinally-extending slits forming an opposed pair of tabs through said tube opening;

(e) positioning a mouth open to a passage of said sheath and formed between said tabs at said seam adjacent to said skin contact surfaces; and

Fig. 1.

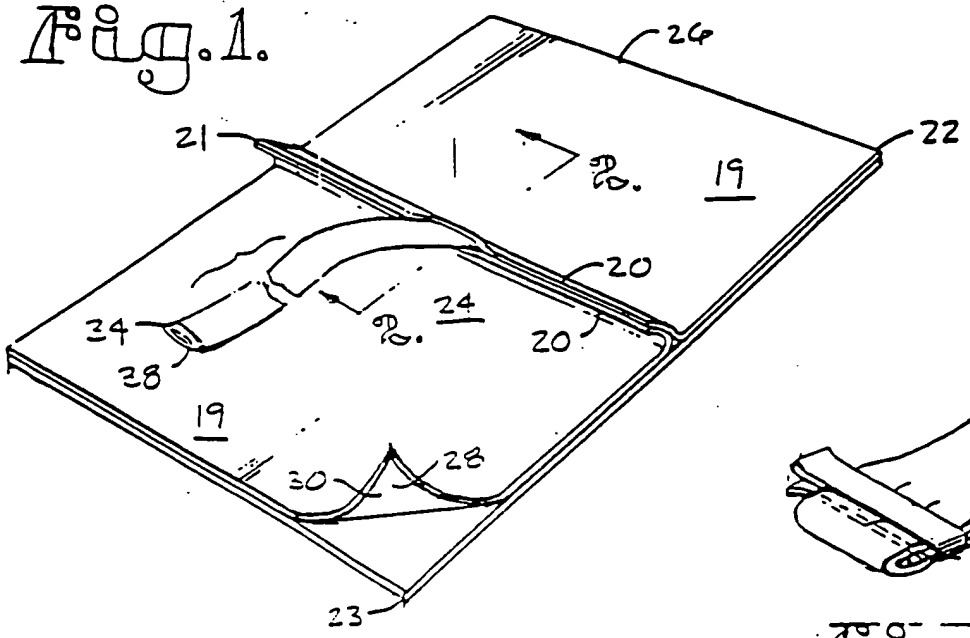


Fig. 5.

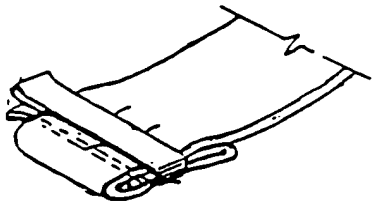


Fig. 2.

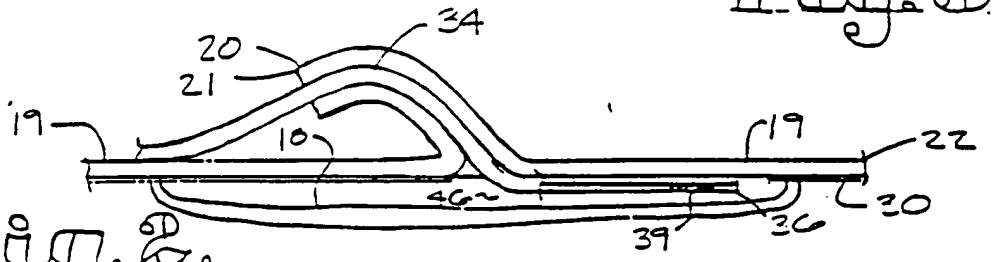
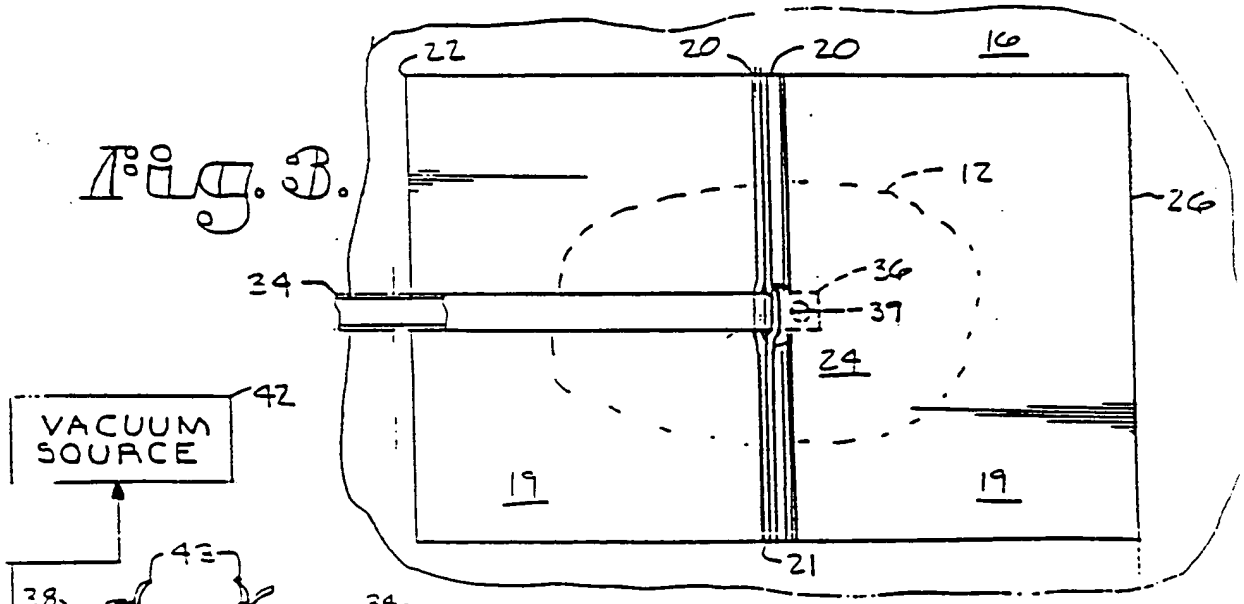


Fig. 3.



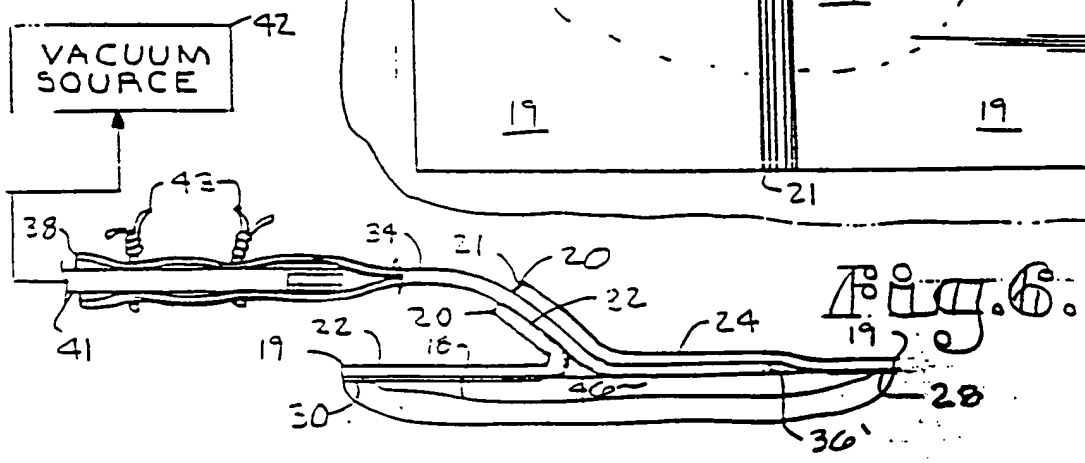


Fig. 6.

Fig. 11.

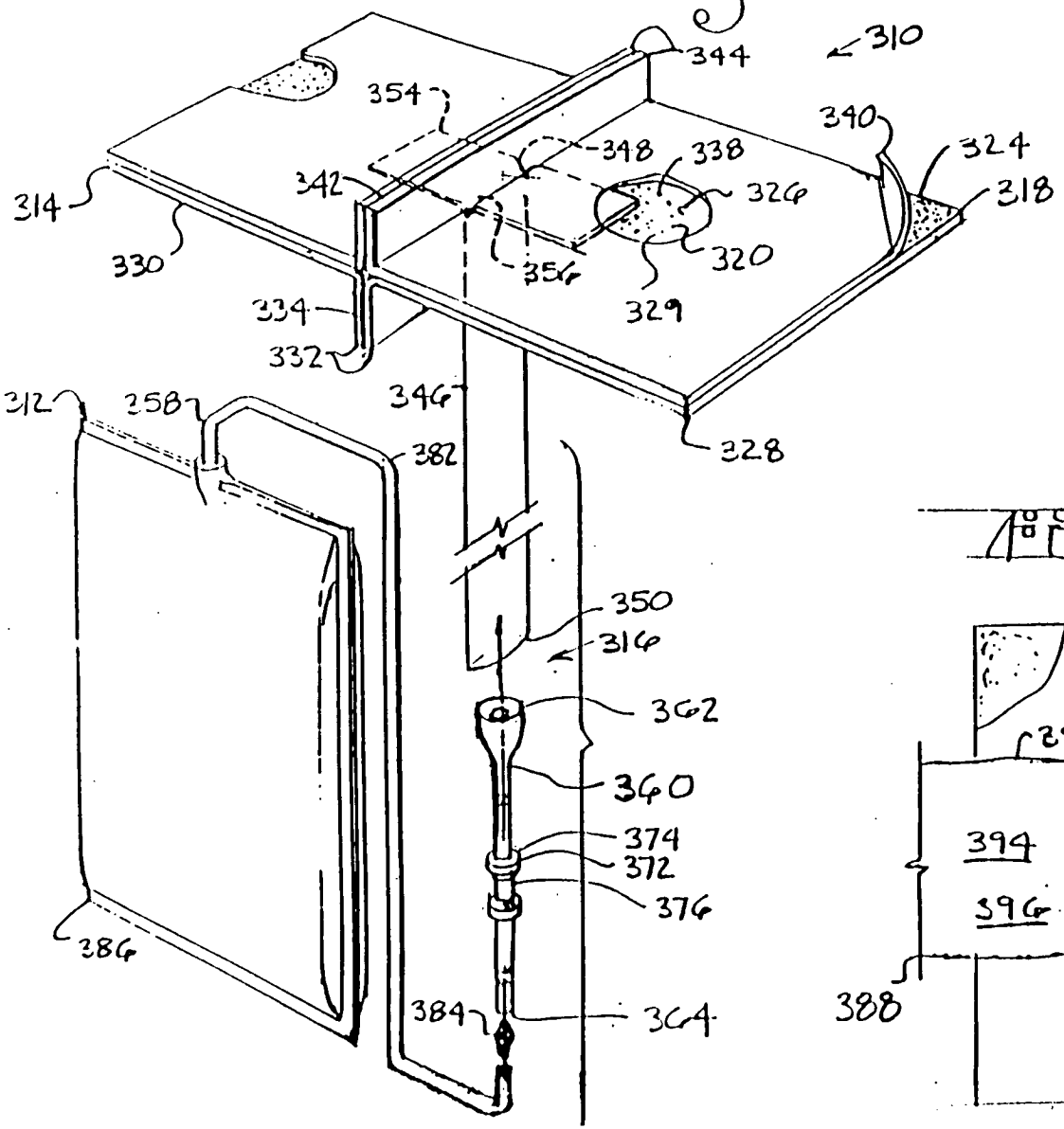


Fig. 14.

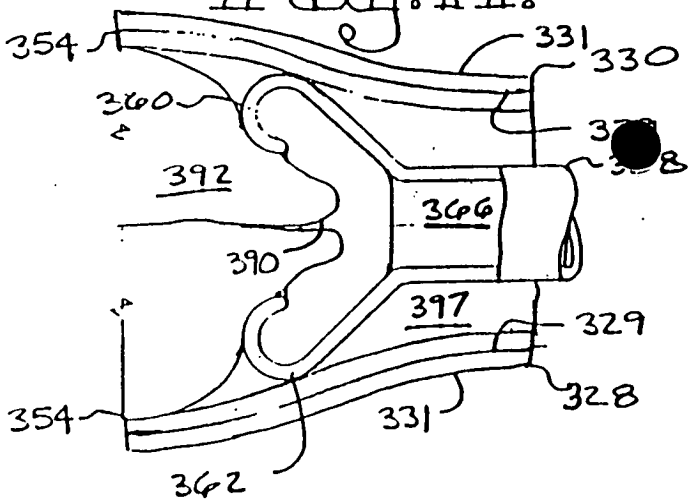
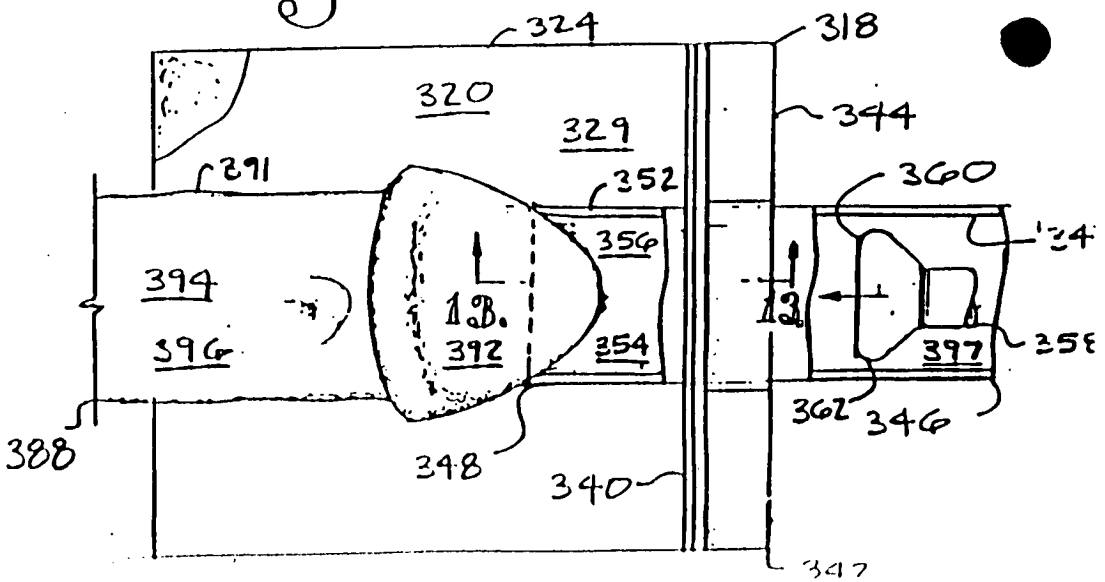


Fig. 12.



INTERNATIONAL SEARCH REPORT

International Application No PCT/US90/01777

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61M 27/00
U.S. CL: 604/305

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	604/174,175,176,179,180,304,305,307,313, 604/346,347,349,353 128/842,844

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
Y	US, A, 3,367,332 (GROVES) 06 February 1968 see entire document	1-24
Y	US, A, 4,080,970 (MILLER) 28 March 1978 see entire document	1,2,4,7,11 14,16,18,22-24
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IV. CERTIFICATION

Date of the Actual Completion of the International Search: 21 MARCH 1990

Date of Mailing of this International Search Report [8]: 06 AUG 1990

International Searching Authority [1]: ISA/US

Signature of Authorized Officer [20]: KATHLEEN A. DALEY

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